

### **REMARKS/ARGUMENTS**

In view of the foregoing amendments and following remarks, favorable reconsideration of the pending claims is requested.

#### **Status of the Claims**

Claims 1 and 2 are pending. Claims 3-5 have been withdrawn.

Claim 1 has been amended replace "sample from a subject" with "sample derived from the peritoneal cavity of a subject" and to replace "aldehyde dehydrogenase" with "mRNA of aldehyde dehydrogenase".

#### ***Amendments to the Specification***

The title of the Invention has been amended to correct a misspelling of the word metastasizing.

Paragraphs [0006], [0007], [0009], [0010], [0019], [0036], and [0052] of the present specification (US 2008/0293043 A1) have been amended to replace "peritoneum" with "peritoneal cavity". This amendment is to correct an error that arose in translating the Japanese priority document.

#### ***Rejections under 35 U.S.C. § 112***

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. Specifically, the Examiner rejects claims 1-2, stating that the specification does not reasonably provide enablement for a method of detecting metastatic cancer cells originating from gastric cancer comprising collecting just any biological sample from a subject and detecting the presence of aldehyde dehydrogenase mRNA or protein in the sample, wherein the presence of aldehyde dehydrogenase mRNA or protein in the sample indicates the presence of metastatic cancer cells originating from gastric cancer in the sample.

As noted above, Claim 1 has been amended to replace "sample from a subject" with "sample derived from the peritoneal cavity of a subject" These amendments clarify that the claimed method uses a sample derived from the peritoneal cavity and that the claimed method detects the presence of mRNA of aldehyde dehydrogenase. The presence of mRNA of aldehyde dehydrogenase in a sample derived from the peritoneal cavity means that the possibility of containing metastatic cancer cells originating from the gastric cancer in the sample is high for the following reason.

As described in section [0011] of the present specification, the inventors have determined that the aldehyde dehydrogenase gene is not expressed in the cells of primary focus of gastric cancer, but is specifically expressed in the cells derived from peritoneally disseminated gastric cancer. Furthermore, as described in section [0036], aldehyde dehydrogenase gene is also not expressed in normal epithelial cells and mesothelial cells in contrast with CEA that had been conventionally used as a detection marker.

Thus, metastatic cancer cells originating from gastric cancer can be detected by determining the presence of expression of aldehyde dehydrogenase gene in a sample that could potentially contain metastatic cancer cells such as peritoneal dissemination. The sample that could potentially contain metastatic cancer cells is a sample derived from the peritoneal cavity, for example, celiac tissues such as peritoneum of the subject, ascites fluid, cells contained in intraoperative peritoneal lavage, and peritoneal lavage fluid (lavage fluid recovered after subjecting to peritoneal lavage) as described in section [0019].

In view of the above, the specification provides enablement for the method for detection of metastatic cancer cells originating from gastric cancer, which is claimed in claim 1. Therefore, the rejection under the Section 112, first paragraph should be withdraw.

***Prior Art Rejections***

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Sakakura et al., British Journal of Cancer, 2002, 87(10):1153-1161.

The Applicants have enclosed the Declaration of coinventors Yoshihide Hayashizaki, Yasushi Okazaki, Chouhei Sakakura, and Hisakazu Yamagishi, which establishes that the Sakakura publication cannot be considered prior art under § 102(a). Yoshihide Hayashizaki, Yasushi Okazaki, Chouhei Sakakura, and Hisakazu Yamagishi are a coinventors of the present application and are also a coauthor of the Sakakura publication. The Declaration states that the Sakakura publication describes the work of Yoshihide Hayashizaki, Yasushi Okazaki, Chouhei Sakakura, and Hisakazu Yamagishi, and is the subject matter described and claimed in the present application.

In paragraph 3, the Declaration states that although A. Hagiwara, M. Nakanishi, K. Shimomura, T. Takagi, R. Yasuoka, Y. Fujita, T. Abe, Y. Ichikawa, S Takahashi, T. Ishikawa, I.

Nishizuka, T. Morita, and H. Shimade are co-authors of the Sakakura publication, they are not co-inventors of the subject matter described and claimed in the '678 Application. As noted in the Declaration, coauthors A. Hagiwara, M. Nakanishi, K. Shimomura, T. Takagi, R. Yasuoka, Y. Fujita, and T. Abe were graduate students that worked at the direction and supervision of the inventors; coauthors Y. Ichikawa, S Takahashi, T. Ishikawa, I. Nishizuka, and T. Morita learned experimental techniques and also worked at the direction and supervision of the inventors; and H. Shimade was also included as coauthor because he was an academic supervisor to Y. Ichikawa, S Takahashi, T. Ishikawa, I. Nishizuka, and T. Morita. Thus, A. Hagiwara, M. Nakanishi, K. Shimomura, T. Takagi, R. Yasuoka, Y. Fujita, T. Abe, Y. Ichikawa, S Takahashi, T. Ishikawa, I. Nishizuka, T. Morita, and H. Shimade cannot be considered as coinventors of the subject matter described in the Sakakura publication.

According to the statute, a person is not entitled to a patent if it was described in a printed publication by others before the invention thereof by the applicant. In the present case, the cited reference describes Applicants' own work. As set forth in MPEP 2132.01, a rejection under 102(a) can be "overcome by submission of a specific declaration by the applicant that the article is describing applicants' own work." In the present case, Applicants' have submitted the Declaration of Yoshihide Hayashizaki, Yasushi Okazaki, Chouhei Sakakura, and Hisakazu Yamagishi that establishes that the Sakakura publication describes their own work and cannot be considered "by others". Thus, it is respectfully submitted that the Sakakura publication cannot be considered prior art under 35 U.S.C. § 102(a), and therefore the rejections under 35 U.S.C. 102(a) have been overcome.

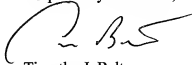
In view of the remarks made above, Applicant submits that the pending rejections have been overcome and that the pending claims are now in condition for allowance and an indication of allowability of the claims is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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